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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,596	03/18/2004	Michael Lange	905.020US2	9548

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EXAMINER

CHANG, CHING

ART UNIT	PAPER NUMBER
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3748

DATE MAILED: 07/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/804,598	LANGE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ching Chang	3748	

**- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -  
Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 February 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 17-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-946)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Office Action is in response to the amendment filed on 02/22/2006.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 17-25, and 26-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

More specifically, " a side member coupled along the sheath ", " the at least one tab disposed between the side member and the elongate tubular sheath "; and " the side member " in claim 17, and " a sheath hub ", " the sheath coupling member disposed along the sheath hub ", and " along the sheath hub " after " the sheath coupling member " in claim 26 are new matter.

3. Claims 26-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

More specifically, since in claim 26, the claimed subject matter " the side port coupling member " can not be coupled with the claimed subject matter " the sheath coupling member along the sheath hub ", accordingly, the claimed subject matter " the side port coupling member releasably coupled with the sheath coupling member along the sheath hub " in claim 26 is unoperable.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. ***Claims 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scarfone et al. (US Patent 5,300,046) in view of West et al. (US Patent 6,322,541).***

Scarfone discloses a method comprising: providing an introducer (102) including a sheath (106, 110), a side port (124), and a side port assembly (126, 128, 130, 132) coupled with the sheath in a coupled position.

Scarfone discloses the invention as recited above, however, fails to disclose the side port assembly being releasably coupled with the sheath through a side port valve.

The patent to West on the other hand, teaches that it is conventional in the vascular introducer sheath and hemostasis valve art, to utilize a snap-fit connection or a threaded connection, to releasably couple a side port assembly (20) to a hemostasis

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valve (an introducer, 8), through a hub (22) and an end cap (24), with an additional seal valve (26) inbetween to seal the side port of the introducer after the side port assembly is removed from the coupled position.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized the snap-fit or threaded coupling or uncoupling, the releasable side port assembly, and an additional sealing valve as taught by West, to couple or uncouple between the side port of the sheath and the side port assembly in the Scarfone method, since the use thereof would provide a more flexible and durable usage on an introducer application.

**6. *Claims 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scarfone in view of West (as applied to claim 37 above), and further in view of Trinder (US Patent 2,493,326).***

The modified Scarfone method discloses the invention, however, fails to disclose of opening the side port valve with a valve opening component associated with a side port coupling member.

The patent to Trinder on the other hand, teaches that it is conventional in the control of intractable nasal hemorrhages art, to utilize a valve opening component (See Figs. 4-5) to open a side port valve (10, S).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized a side port valve opening component as taught by Trinder in the modified Scarfone method, since the use thereof would provide an improved fluid flowing control method, in an introducer application.

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**7. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scarfone in view of West (as applied to claim 35 above), and further in view of Dressel (US Patent 5,102,410).**

The modified Scarfone method discloses the invention, however, fails to disclose of coupling a cap with the sheath after uncoupling the side port assembly.

The patent to Dressel on the other hand, teaches that it is conventional in the method a soft tissue cutting aspiration art, to couple a sheath with a cap (60) after uncoupling a side port assembly.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have coupled a sheath with a cap (60) after uncoupling a side port assembly, as taught by Dressel in the modified Scarfone method, since the use thereof would provide an improved method to prevent fluid leak from an introducer.

**8. Claims 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. (US Patent 5,755,693) in view of Scarfone et al. (US Patent 5,300,046), and further in view of West et al. (US Patent 6,322,541).**

Walker discloses a method comprising: providing an introducer (10) including a sheath (18).

Walker discloses the invention, however, fails to disclose a side port, and a side port assembly being coupled with the sheath in a coupled position.

The patent to Scarfone on the other hand, teaches that it is conventional in the sheath catheter assembly art, to utilize a side port assembly (See Figs. 1-2) attached to sheath catheter assembly (102), through a side port (124).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized a side port assembly attached to the sheath as taught by Scarfone in the Walker method, since the use thereof would provide an improved sheath introducer, with additional fluid flowing through as needed.

The modified Walker method discloses the invention as recited above, however, fails to disclose the side port assembly being releasably coupled with the sheath through a side port valve.

The patent to West on the other hand, teaches that it is conventional in the vascular introducer sheath and hemostasis valve art, to utilize a snap-fit connection or a threaded connection, to releasably couple a side port assembly (20) to a hemostasis valve (an introducer, 8), through a hub (22) and an end cap (24), with an additional seal valve (26) inbetween to seal the side port of the introducer after the side port assembly is removed from the coupled position.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized the snap-fit or threaded coupling or uncoupling, the releasable side port assembly, and an additional sealing valve as taught by West, to couple or uncouple between the side port of the sheath and the side port assembly in the modified Walker method, since the use thereof would provide a more flexible and durable usage on an introducer application.

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9. ***Claims 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. in view of Scarfone, further in view of West (as applied to claim 37 above), and further in view of Trinder (US Patent 2,493,326).***

The modified Walker method discloses the invention, however, fails to disclose of opening the side port valve with a valve opening component associated with a side port coupling member.

The patent to Trinder on the other hand, teaches that it is conventional in the control of intractable nasal hemorrhages art, to utilize a valve opening component (See Figs. 4-5) to open a side port valve (10, S).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized a side port valve opening component as taught by Trinder in the modified Walker method, since the use thereof would provide an improved fluid flowing control method, in an introducer application.

10. ***Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. in view of Scarfone, further in view of West (as applied to claim 35 above), and further in view of Dressel (US Patent 5,102,410).***

The modified Walker method discloses the invention, however, fails to disclose of coupling a cap with the sheath after uncoupling the side port assembly.

The patent to Dressel on the other hand, teaches that it is conventional in the method a soft tissue cutting aspiration art, to couple a sheath with a cap (60) after uncoupling a side port assembly.



It would have been obvious to one having ordinary skill in the art at the time the invention was made to have coupled a sheath with a cap (60) after uncoupling a side port assembly, as taught by Dressel in the modified Walker method, since the use thereof would provide an improved method to prevent fluid leak from an introducer.

### ***Response to Arguments***

11. Applicant's arguments filed on 02/22/2006 have been fully considered but they are not persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this instant application, regarding the 35 USC 103(a) rejections to claims 35-40, the Scarfone reference discloses a method of providing an introducer (102) including a sheath (106, 110), a side port (124), and a side port assembly (126, 128, 130, 132) coupled with the sheath in a coupled position, the teaching of West reference is to utilize a snap-fit connection or a threaded connection, to releasably couple a side port assembly (20) to a hemostasis valve (an introducer, 8), through a hub (22) and an end cap (24), with an additional seal valve (26) inbetween to seal the side port of the introducer after the side port assembly

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is removed from the coupled position, accordingly, the Examiner deems that It would have been obvious to one having ordinary skill in the art at the time the invention was made, to have utilized the snap-fit or threaded coupling or uncoupling, the releasable side port assembly, and an additional sealing valve as taught by West, to couple or uncouple between the side port of the sheath and the side port assembly in the Scarfone method, since the use thereof would provide a more flexible and durable usage on an introducer application.

Additionally, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., " The cited references fail to enable a releasable side port that is releasably coupled with the sheath " (See The Second Paragraph, Page 7 of the Attorney's Remarks)) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

### **Conclusion**

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ching Chang whose telephone number is (571)272-4857. The examiner can normally be reached on M-Th, 7:00 AM -5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Denion can be reached on (571)272-4859. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Patent Examiner



Ching Chang



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